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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,704

02/16/2006

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EXAMINER

MI, QIUWEN

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

10/29/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No. 10/568,704	Applicant(s) BORTLIK ET AL.	
	Examiner QIUWEN MI	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 12, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment in the reply filed on 10/6/08 is acknowledged. Claim 13 is cancelled. Claims 1-12, 14, and 15 are pending. Claims 6-8, 12, 14, and 15 are withdrawn as they are directed toward a non-elected invention group. **Claims 1-5, and 9-11 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, and 9-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bortlik et al (US 2002/0107292), in view of Zelkha et al (US 5,837,311).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 7/7/2008, repeated below, slightly altered to take into consideration Applicant's amendment filed on 10/6/08. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

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Bortlik et al disclose a cosmetic composition, milk for the face (water soluble at room temperature), comprising 2% powder according to Example 1 (containing whey protein isolate, lycopene, and oleoresin (lipid, contains resin acid, see Wikipedia online) [0050]), 0.4% carboxyvinyl polymer (polysaccharides), 3% soybean protein, and reminder being water [0059]. Bortlik et al teach that the invention relates to methods of forming the primary composition, the food supplement, cosmetic preparation or pharmaceutical preparation containing the same, and to a method for protecting skin tissue against ageing by administering to a subject in need of such protection one of the primary, oral, or cosmetic compositions disclosed herein [0008]. Bortlik et al further teach that the composition can be provided in the form of a powder (pulverulent), liquid or gel [0015], the composition can additionally comprise vitamin E and vitamin C (ascorbic acid, organic acid) [0018]. At last, Bortlik et al teach that the composition enhance the bioavailability of the lipophilic bioactive compound in the body and to slow down the aging of the skin [0023].

Bortlik et al do not teach the concentrate is isolated from fibers and other insoluble compounds by solid-lipid separation, or the concentrate is extracted from a lycopene-containing material without the use of a solvent, or the exact claimed amount of the components in the composition.

Zelkha et al teach the lycopene extract (thus a concentrate) is separated from the pulp, preferably by means of a continuous decanter, and is then filtered. Preferably, the filtration is in two stages, a crude one and a fine one, to ensure the removal of even the very fine particles of pulp (thus a solid-liquid separation). The last fiber preferably has a mesh size of 2 micron (thus

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substantially free of other insoluble compounds) (col 7, lines 55-62). Zelkha et al also teach that the tomato oleoresin contains a high concentration of lycopene, which can be used as a natural coloring material, e.g., in beverages, drinks, foodstuffs, cosmetics, etc (col 6, lines 7-13). Zelkha et al further teach that the invention provides a process for the production of lycopene-containing oleoresin from tomatoes in the most efficient manner, in particular for obtaining oleoresin having an optimal combination of high lycopene content and lycopene stability (col 2, lines 8-14).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the inventions of Bortlik et al since Bortlik et al teach that the composition enhance the bioavailability of the lipophilic bioactive compound in the body and to slow down the aging of the skin.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the filtration steps of Zelkha et al to remove pulp (fiber) and other insoluble compounds since Zelkha et al that the process provides the production of lycopene-containing oleoresin from tomatoes in the most efficient manner, in particular for obtaining oleoresin having an optimal combination of high lycopene content and lycopene stability.

Since both of the inventions yielded beneficial results in food and cosmetic industry, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of the components in the composition, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does

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not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that “the cited references fail to disclose or suggest a natural lycopene concentrate, wherein the concentrate is extracted from a lycopene-containing material without the use of a solvent as required, in part, by the present claims. *Bortlik* is entirely directed to a lipophilic bioactive extract obtained by the use of a solvent. See, *Bortlik*, paragraph 9, lines 4-14. *Bortlik* specifically discloses that its lycopene extract is “obtained by conventional methods, with the preferred totmato [*sic*] extract being a lipidic extract obtained by use of a solvent such as ethyl acetate.” See, *Bortlik*, paragraph 14, lines 8-10. In fact, all of the embodiments and examples disclosed in *Bortlik* involve the use of a solvent to obtain the lipophilic bioactive compound. See, *Bortlik*, paragraphs 32-37, 40 and 49-51. Therefore, *Bortlik* fails to disclose or suggest a natural lycopene concentrate, wherein the concentrate is extracted from a lycopene-containing material without the use of a solvent” (page 7, last paragraph bridging page 8).

Applicant also argues that “*Zelkha* is also directed to the use of a solvent to obtain a lycopene oleoresin. See, *Zelkha*, Abstract, lines 6-10. For example, the process of *Zelkha* comprises the step of subjecting a tomato pulp to solvent extraction in order to obtain an oleoresin containing

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lycopene. See, *Zelkha*, column 2, lines 28-40. Although *Zelkha* discloses that the tomato pulp may be extracted using solvents or finely ground into a new product, the finely ground product contains most of the tomato insoluble solids and is not a lycopene concentrate that is isolated from fibers and other insoluble compounds as required by the present claims. See, *Zelkha*, column 3, lines 49- 55. As the Patent Office admits, the lycopene concentrate of *Zelkha* is the lycopene oleoresin that is extracted from the tomato. See, Office Action, page 4, lines 23-24; page 5, lines 1-8. The lycopene oleoresin is "obtained by an appropriate choice of solvents." See, *Zelkha*, column 4, lines 57-65; column 5, lines 14-16. As such, the cited references fail to disclose or suggest a natural lycopene concentrate, wherein the concentrate is extracted from a lycopene-containing material without the use of a solvent as recited, in part, by the present claims" (page 8, 2nd paragraph).

This is not found persuasive. As indicated above, Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

Applicant argues that "Moreover, the cited references fail to disclose or suggest a natural lycopene concentrate that is isolated from fibers and other insoluble compounds by solid-liquid separation as required, in part, by the present claims. The Patent Office admits that *Bortlik* fails to disclose or suggest that the concentrate is free or isolated from fibers and other insoluble compounds and instead relies on *Zelkha* for the claimed element. See, Office Action, page 4,

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lines 20-24; page 5, lines 1-8 and 13-17. However, the portions of *Zelkha* relied on by the Patent Office merely disclose separating fibers and insoluble solids from a lycopene oleoresin that is obtained by extraction with a solvent. See, *Zelkha*, column 7, lines 49-61. Because the solvent may modify the native characteristics of the lycopene in the oleoresin, the oleoresin is not a natural concentrate. See, Specification, paragraph 20” (page 8, last paragraph). *Zelkha et al* explicitly teach

This is not found persuasive. *Zelkha et al* explicitly teach the lycopene extract (thus a concentrate) is separated from the pulp, preferably by means of a continuous decanter, and is then filtered. Preferably, the filtration is in two stages, a crude one and a fine one, to ensure the removal of even the very fine particles of pulp, thus *Zelkha et al* explicitly teach a solid-liquid separation. Furthermore, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/

Primary Examiner, Art Unit 1655